



DEPARTMENT OF HEALTH & HUMAN SERVICES

JUN 2 2012

Food and Drug Administration
Rockville MD 20857

Re: Gore Tag CTAG Thoracic
Endoprosthesis Device
Docket No. FDA-2012-E-0033

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is concerning the application for patent term extension for U.S. Patent No. 6,042,605 filed by Gore Enterprise Holdings, Inc. under 35 U.S.C. 156. The medical device claimed by the patent is Gore Tag CTAG Thoracic Endoprosthesis Device, which was assigned premarket approval application (PMA) No. P40043, Supplement 039.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. 156(a)(4). However, our records also indicate that the Gore Tag CTAG Thoracic Endoprosthesis Device was not a new device and does not represent the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. 156(f)(1). Instead, it was a design modification of the previously approved Gore Tag Thoracic Endoprosthesis Device.

The PMA Supplement 039 was approved on August 23, 2011, which makes the submission of the patent term extension application on October 21, 2011, timely within the meaning of 35 U.S.C. 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Gilbert R. Gabo
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